

US009604217B2

(12) United States Patent

Palmer et al.

(54) SPECIMEN CONTAINER LABEL FOR AUTOMATED CLINICAL LABORATORY PROCESSING SYSTEMS

(71) Applicant: Becton, Dickinson and Company,

Franklin Lakes, NJ (US)

(72) Inventors: Ashley Palmer, Englewood, NJ (US);

Robert S. Ross, Hacienda Heights, CA (US); Paul Holmes, New York, NY (US); Robert S. Golabek, Jr., Towaco, NJ (US); Shenika E. Felix, Hewitt, NJ (US); Nancy Dubrowny, Garfield, NJ (US); Kristine Conley, North Haledon, NJ (US); Christine Bush, Wayne, NJ

(US)

(73) Assignee: Becton, Dickinson and Company,

Franklin Lakes, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 66 days.

This patent is subject to a terminal dis-

claimer.

(21) Appl. No.: 14/608,467

(22) Filed: Jan. 29, 2015

(65) Prior Publication Data

US 2015/0135813 A1 May 21, 2015

Related U.S. Application Data

(62) Division of application No. 13/295,251, filed on Nov. 14, 2011, now Pat. No. 8,973,293.

(Continued)

(51) **Int. Cl.**

 $G09F \ 3/10$ (2006.01) $B01L \ 3/00$ (2006.01)

(Continued)

(10) Patent No.: US 9,604,217 B2

(45) Date of Patent: *Mar. 28, 2017

(52) U.S. Cl.

(Continued)

(58) Field of Classification Search

CPC A61B 6/5294; G01B 2035/00861; B01L 3/5453

(Continued)

(56) References Cited

U.S. PATENT DOCUMENTS

2,127,043 A * 8/1938 Most B29C 70/58 156/303.1

3,266,298 A 8/1966 Whitehead et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP 510615 A1 10/1992 EP 0486059 B1 1/1997 (Continued)

OTHER PUBLICATIONS

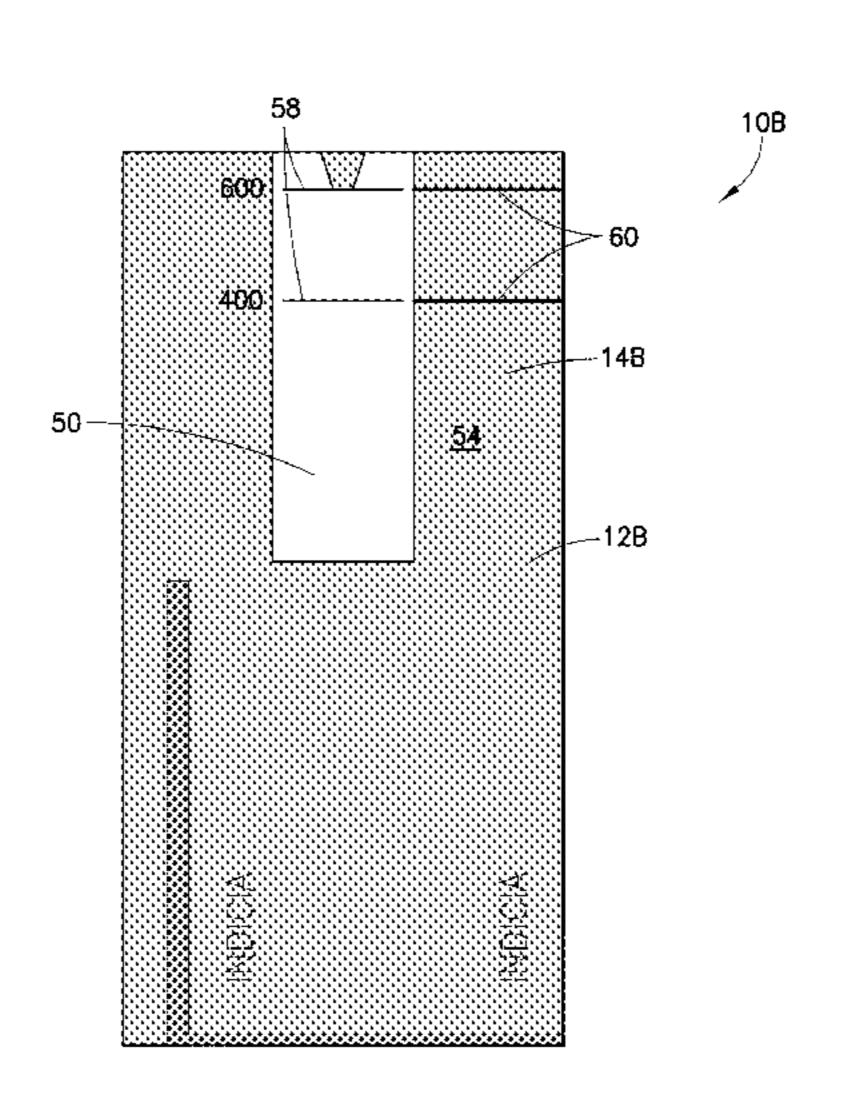
Brady Laboratory Identification: Providing Solutions with: Labels, Printers, Software and Barcode Scanners, www.BradyID.com/lab (2013).

Primary Examiner — Kristina Junge (74) Attorney Agent or Firm — The Web

(74) Attorney, Agent, or Firm — The Webb Law Firm

(57) ABSTRACT

A label and labeling system for identifying the volume of a specimen within a specimen collection container are disclosed. The system includes providing a specimen collection container having an open top end, a closed bottom end, and a sidewall extending therebetween forming an interior adapted for receiving a specimen therein. The specimen collection container also includes a label having a label body disposed over at least a portion of the sidewall, in visual alignment with a colored background. At least one of the (Continued)



sidewall of the specimen collection container and the label				
body have printing disposed thereon having a color that is				
substantially identical to the colored background against				
which the specimen collection container will be viewed. At				
least one of the sidewall of the specimen collection container				
and the label body may have colorless indicia having a				
surface enhancement feature for providing visual distinc-				
tion.				

5 Claims, 13 Drawing Sheets

Related U.S. Application Data

(60)	Provisional application No. 61/415,665, filed on Nov.
	19, 2010.

(51) Int. Cl. G01F 17/00 (2006.01) A61B 6/00 (2006.01) G01N 35/00 (2006.01)

(52) **U.S. Cl.**CPC *B01L 3/5082* (2013.01); *B01L 2300/021*(2013.01); *B01L 2300/0832* (2013.01); *B01L*2300/168 (2013.01); *G01N 2035/00861*(2013.01); *G09F 3/10* (2013.01)

(56) References Cited

U.S. PATENT DOCUMENTS

3,482,082 A	12/1969	Isreeli
3,553,041 A	1/1971	Von Hofe
3,619,568 A	11/1971	Taplin
3,653,176 A	4/1972	Gess
3,656,473 A	4/1972	Sodickson et al.
3,843,440 A	10/1974	Davies
3,898,433 A	8/1975	Sallet
3,985,605 A	10/1976	Treiber et al.
4,015,352 A	4/1977	Prange
4,122,947 A	10/1978	Falla
4,292,916 A	10/1981	Bradley et al.
4,344,994 A	8/1982	Batty et al.
4,397,318 A	8/1983	Burns
4,411,163 A	10/1983	White
4,480,470 A	11/1984	Tussing
4,576,185 A	3/1986	Proud et al.
4,589,141 A	5/1986	Christian et al.
D285,115 S	8/1986	Proud et al.
4,626,314 A	12/1986	Wesley
4,646,753 A	3/1987	Nugent
4,654,127 A	3/1987	Baker et al.
4,690,153 A	9/1987	Losada et al.
4,763,930 A	8/1988	Matney
4,828,716 A	5/1989	McEwen et al.
4,873,193 A	10/1989	Jensen et al.
4,964,413 A	10/1990	Losada et al.
4,967,763 A	11/1990	Nugent et al.
5,025,798 A	6/1991	Schindele
5,038,794 A	8/1991	Van Valkenburg
5,061,263 A	10/1991	Yamazaki et al.
5,143,084 A	9/1992	Macemon et al.
5,150,795 A	9/1992	Nakayama
5,164,575 A	11/1992	Neeley et al.
5,220,302 A	6/1993	Nunnally et al.
5,288,466 A	2/1994	Burns
5,384,096 A	1/1995	Burns
D256 642 G	0/1005	D

3/1995 Burns

3/1995 Neeley

D356,643 S

5,401,110 A

```
D357,985 S
                    5/1995 Burns
                   10/1995 Burns
    5,458,113 A
    5,458,854 A
                   10/1995 Burns
   5,494,170 A
                    2/1996 Burns
   5,527,513 A
                    6/1996 Burns
   5,552,117 A
                    9/1996 Burns
                    5/1997 Haas et al.
   5,633,835 A
   5,672,321 A
                    9/1997 Daykin
    5,688,361 A
                   11/1997 Itoh
   5,699,923 A
                   12/1997 Burns
    5,711,875 A
                    1/1998 Kayal et al.
    5,738,233 A
                    4/1998 Burns
   5,743,861 A
                    4/1998 Columbus et al.
   5,793,030 A
                    8/1998 Kelly, Jr.
                   10/1999 Simons et al.
    5,971,941 A
   6,017,318 A
                    1/2000 Gauthier et al.
                    2/2000 Levy
   6,030,582 A
                    3/2000 Grosskopf et al.
   6,035,568 A
                    5/2000 Niermann
   D425,625 S
                    5/2000 Sarstedt
   6,056,925 A
   6,120,481 A *
                    9/2000 Rennert ...... A61M 5/3129
                                                 604/186
   6,209,921 B1
                    4/2001 Hogan et al.
                    4/2001 Fung et al.
   6,221,655 B1
   6,279,759 B1
                    8/2001 Weisbach
                    1/2002 Compton
   6,335,692 B1
   6,358,476 B1
                    3/2002 Innamorato et al.
   6,373,786 B1
                    4/2002 Kagan et al.
   6,391,262 B1
                    5/2002 Brinton et al.
                    7/2002 Rosen et al.
   6,426,049 B1
                    8/2002 Stevens et al.
   6,428,640 B1
   6,533,015 B1
                    3/2003 Moore
                    4/2003 Cohen et al.
   6,551,267 B1
                    5/2003 Rosen et al.
   6,562,300 B2
   6,808,574 B1
                   10/2004 Stevens et al.
   6,891,182 B2
                    5/2005 Watari et al.
                    3/2009 Tribble et al.
   7,499,581 B2
                   6/2011 Wilkinson
   D640,797 S
                   9/2011 Wilkinson
   D645,972 S
                   12/2001 Bierre .....
                                            B01L 3/5453
2001/0049147 A1*
                                                 436/165
2002/0154809 A1
                   10/2002 Yamagishi et al.
2002/0156439 A1
                   10/2002 Iskra
                   12/2003 Wien et al.
2003/0235119 A1
2004/0171168 A1
                    9/2004 Itoh
2004/0176704 A1
                    9/2004 Stevens
                   10/2004 Stevens et al.
2004/0200558 A1
                   12/2004 Ribi
2004/0257918 A1
2006/0091669 A1
                    5/2006 Wilkinson
2006/0222802 A1
                   10/2006 Stevens et al.
2006/0249582 A1
                   11/2006 Golabek et al.
                    4/2007 Skinner
2007/0092585 A1
                    5/2008 Carano et al.
2008/0125673 A1
2009/0193696 A1
                    8/2009 Golabek et al.
                    1/2010 Ostgaard et al.
2010/0021343 A1
2010/0067024 A1
                    3/2010 Swenson et al.
                    7/2011 Wilkinson et al.
2011/0178424 A1
         FOREIGN PATENT DOCUMENTS
```

		1 DOCC
EP	0992287 A2	4/2000
EP	1004359 A2	5/2000
JP	56092262 U	7/1981
JP	1-156667 A	6/1989
JP	3041365 A	2/1991
JP	03-063570 A	3/1991
JP	4-63484 U	5/1992
JP	05-095936 A	4/1993
JP	5097133 A	4/1993
JP	5143794 A	6/1993
JP	5-71792 U	9/1993
JP	6-59937	8/1994
JP	07-167716 A	7/1995
JP	8166765 A	6/1996
JP	9-504608 A	5/1997
JP	09133687	5/1997
JP	9-236608 A	9/1997
JP	3048980 U	5/1998
JP	2002-82120 A	3/2002

US 9,604,217 B2 Page 3

(56)	References Cited		
	FOREIGN PATEN	NT DOCUMENTS	
JP	2002-102210 A	4/2002	
JP	2002-243734 A	8/2002	
JP	2003-004875 A	1/2003	
JP	2004-121704 A	4/2004	
JP	2004-347376 A	12/2004	
JP	2005249762	9/2005	
JP	2006106455	4/2006	
WO	01/26993 A1	4/2001	
WO	02/06904 A1	1/2002	
WO	2005/116632 A2	12/2005	
WO	2007092585 A2	8/2007	
WO	2008031036 A1	3/2008	
WO	2008078808 A1	7/2008	
WO	2009111622 A2	9/2009	

^{*} cited by examiner

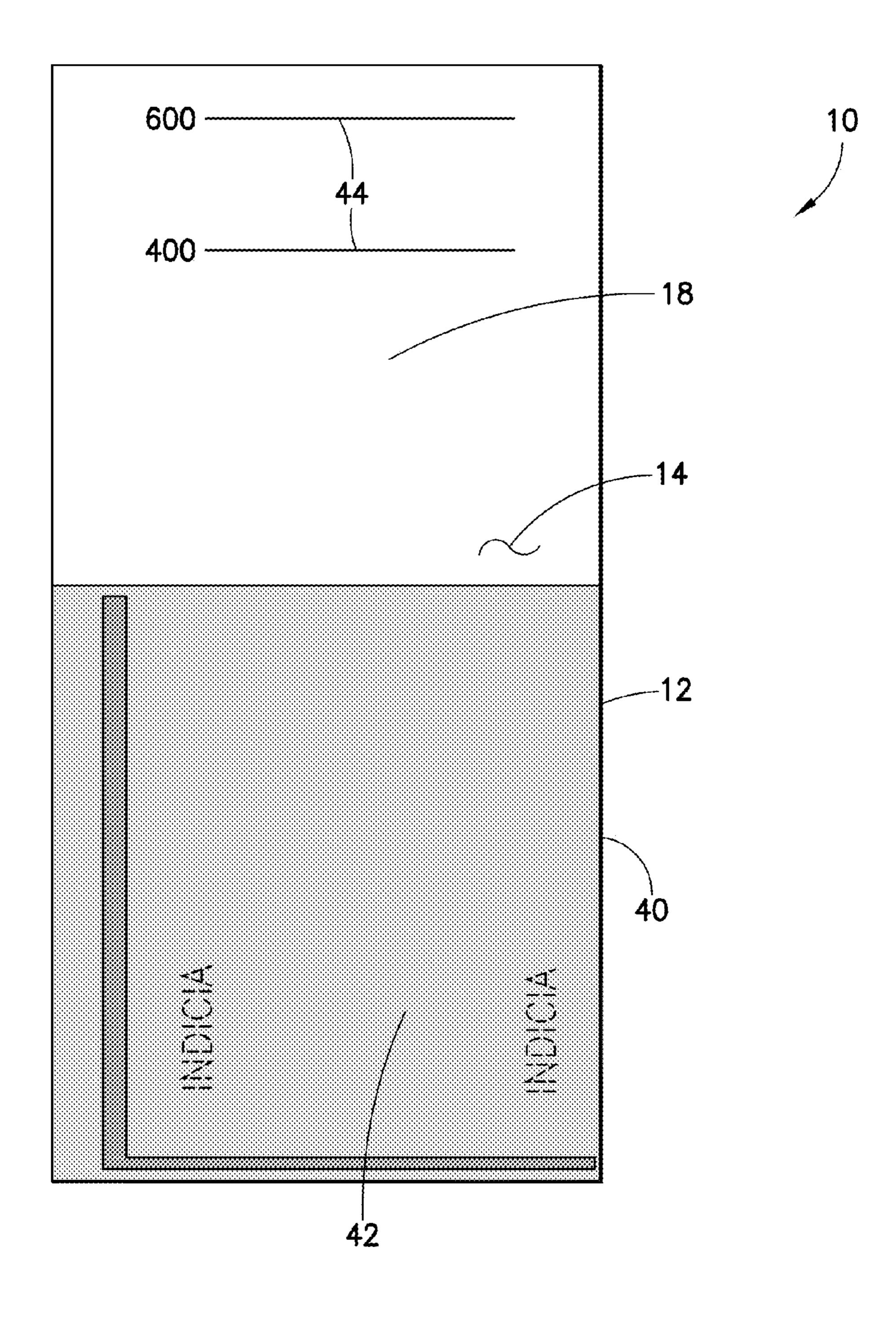


FIG. 1

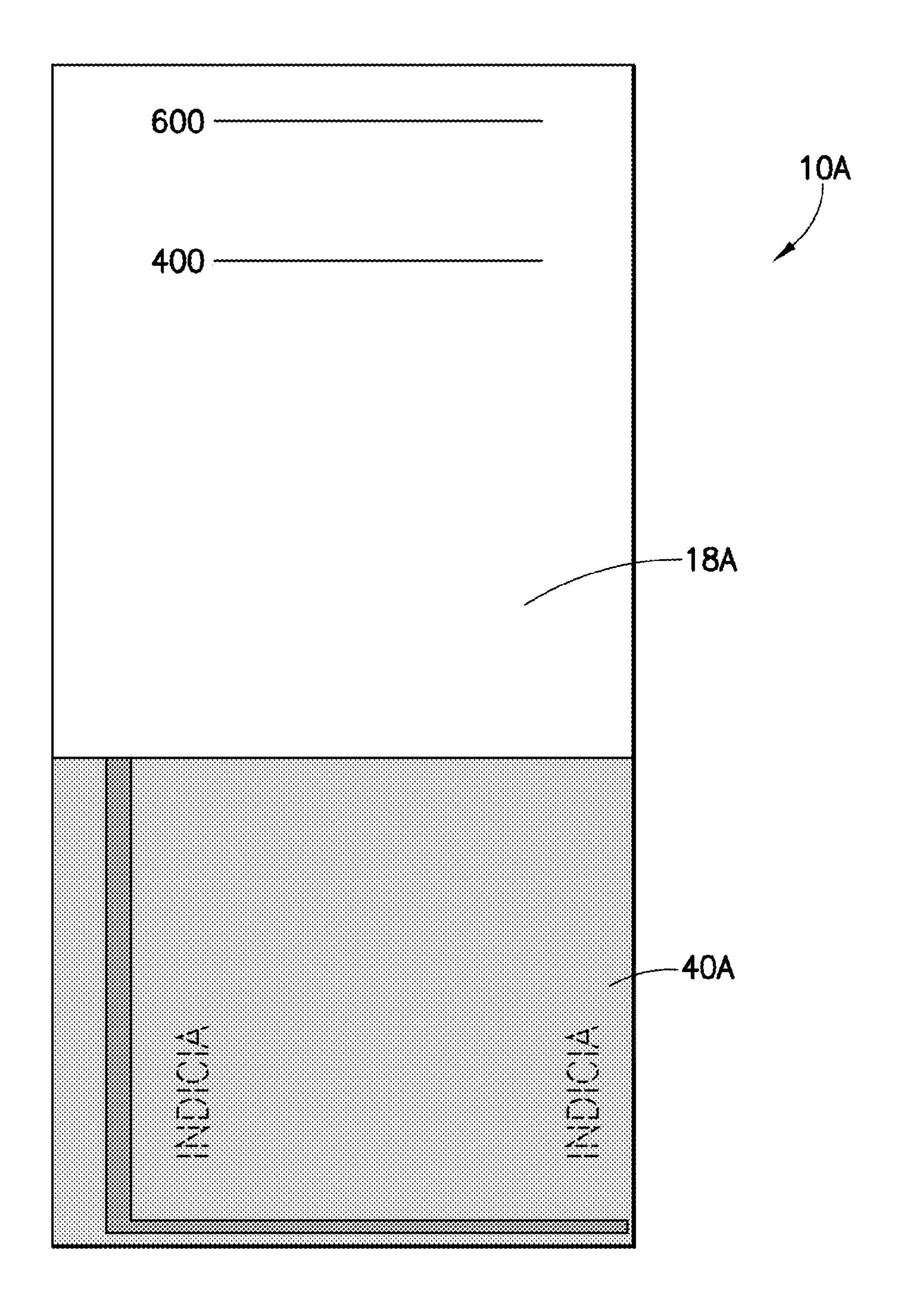
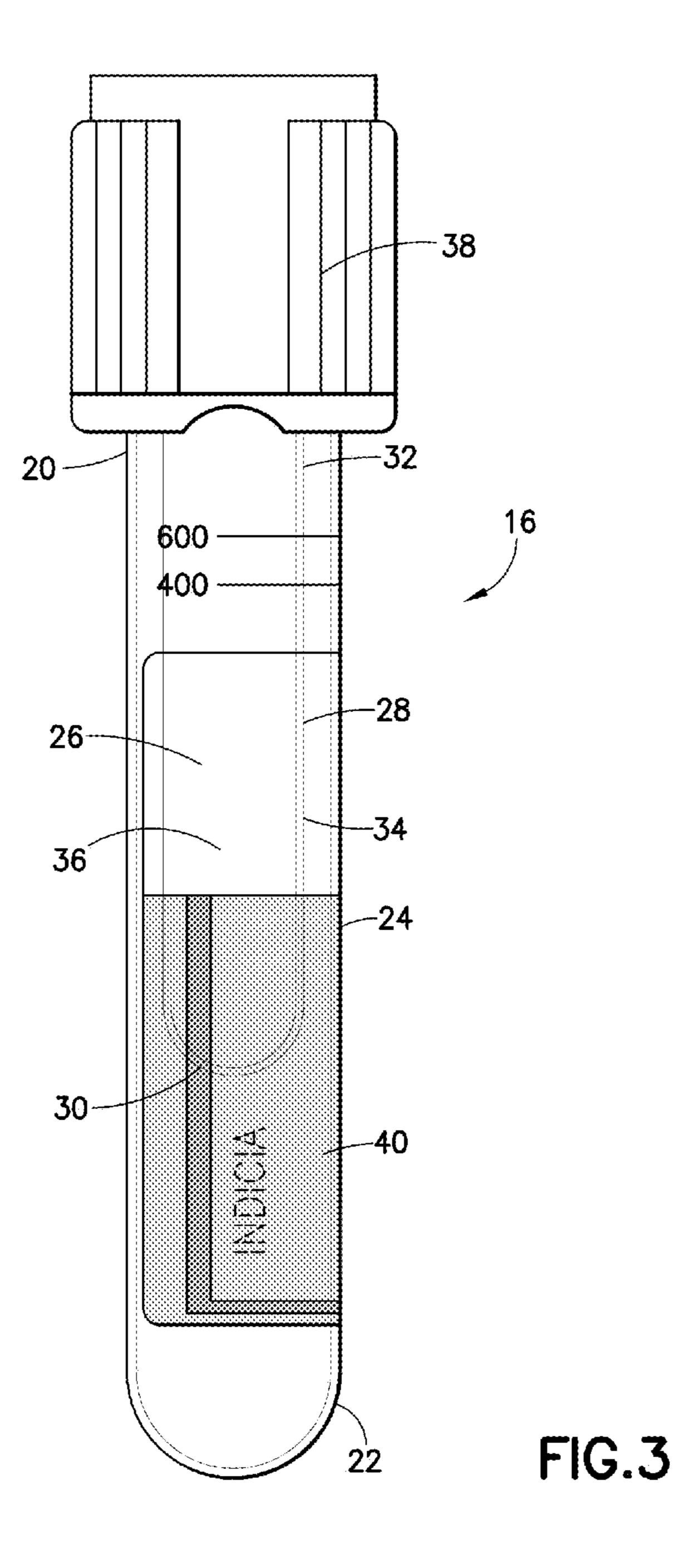
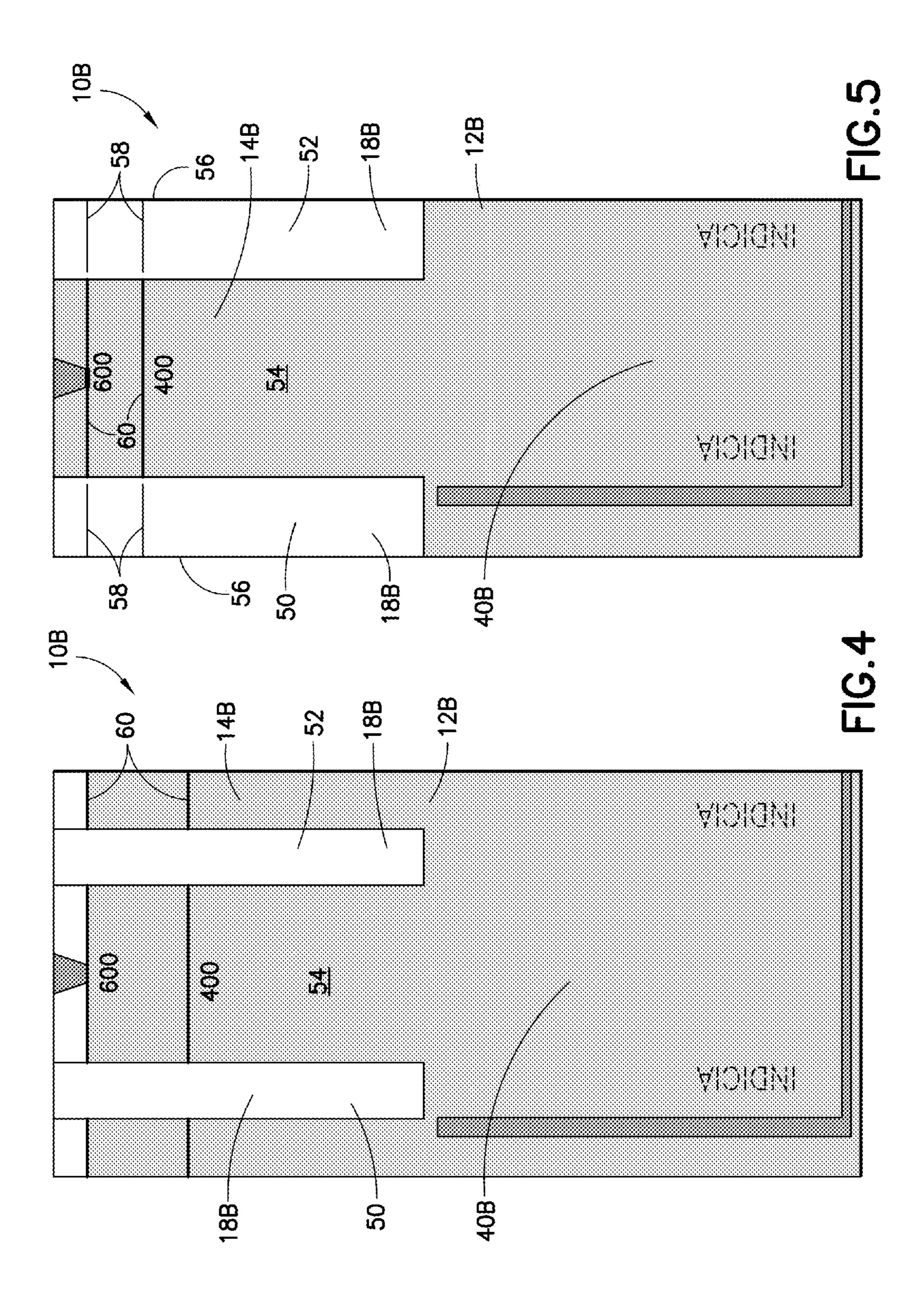


FIG.2





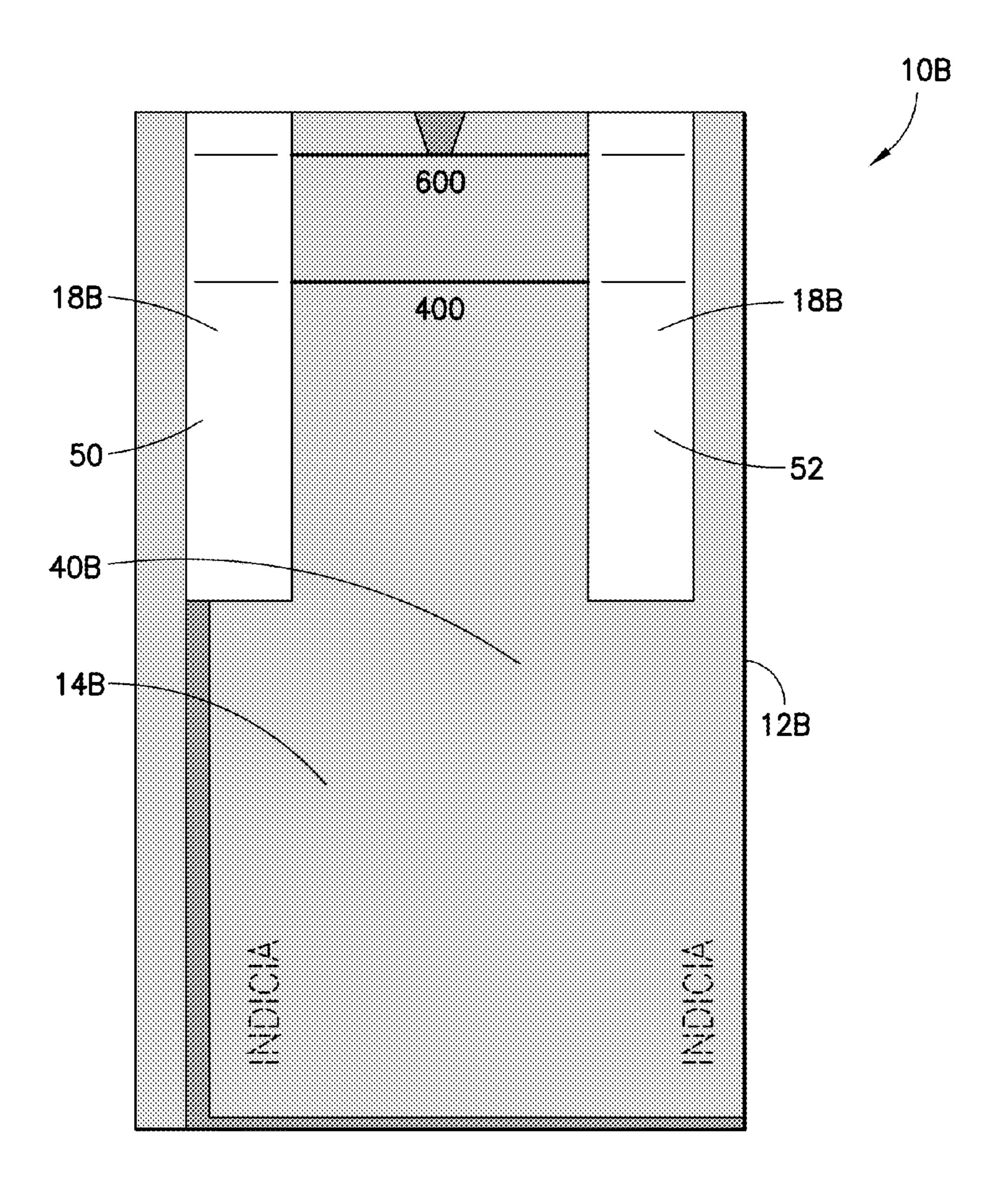
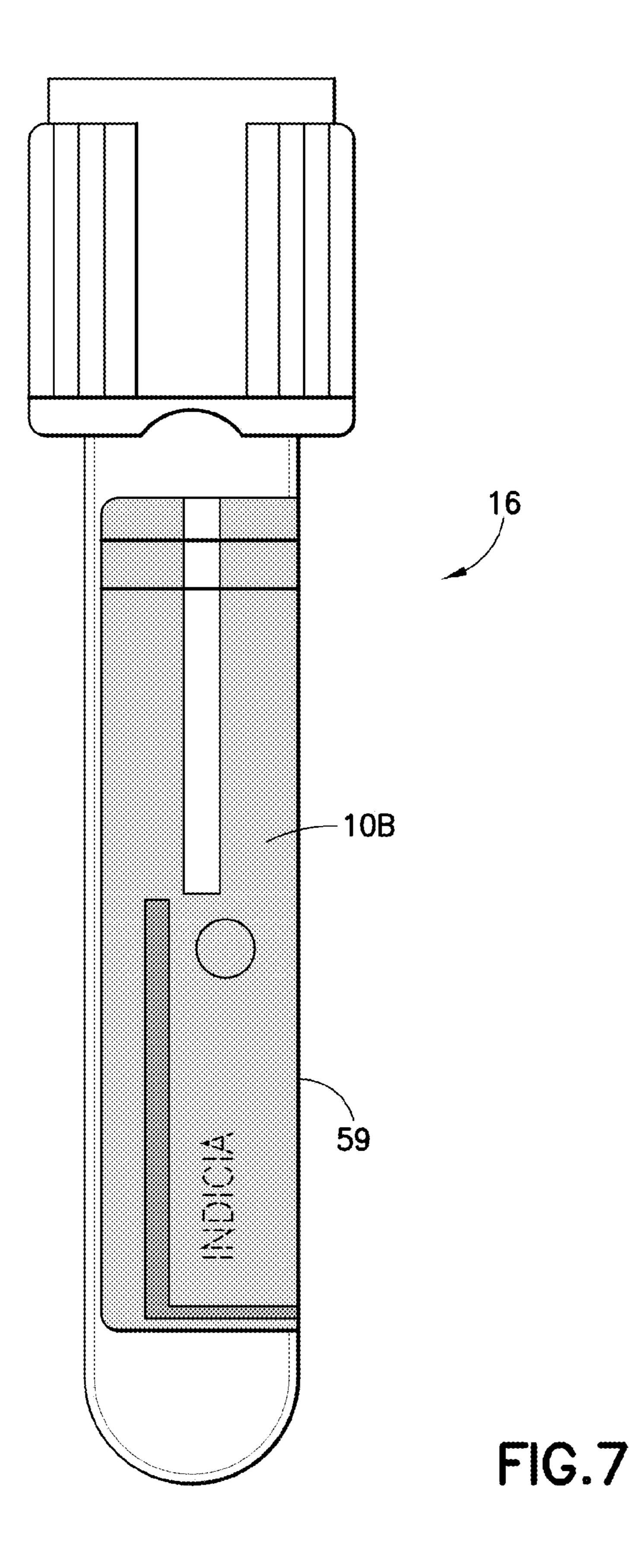


FIG.6



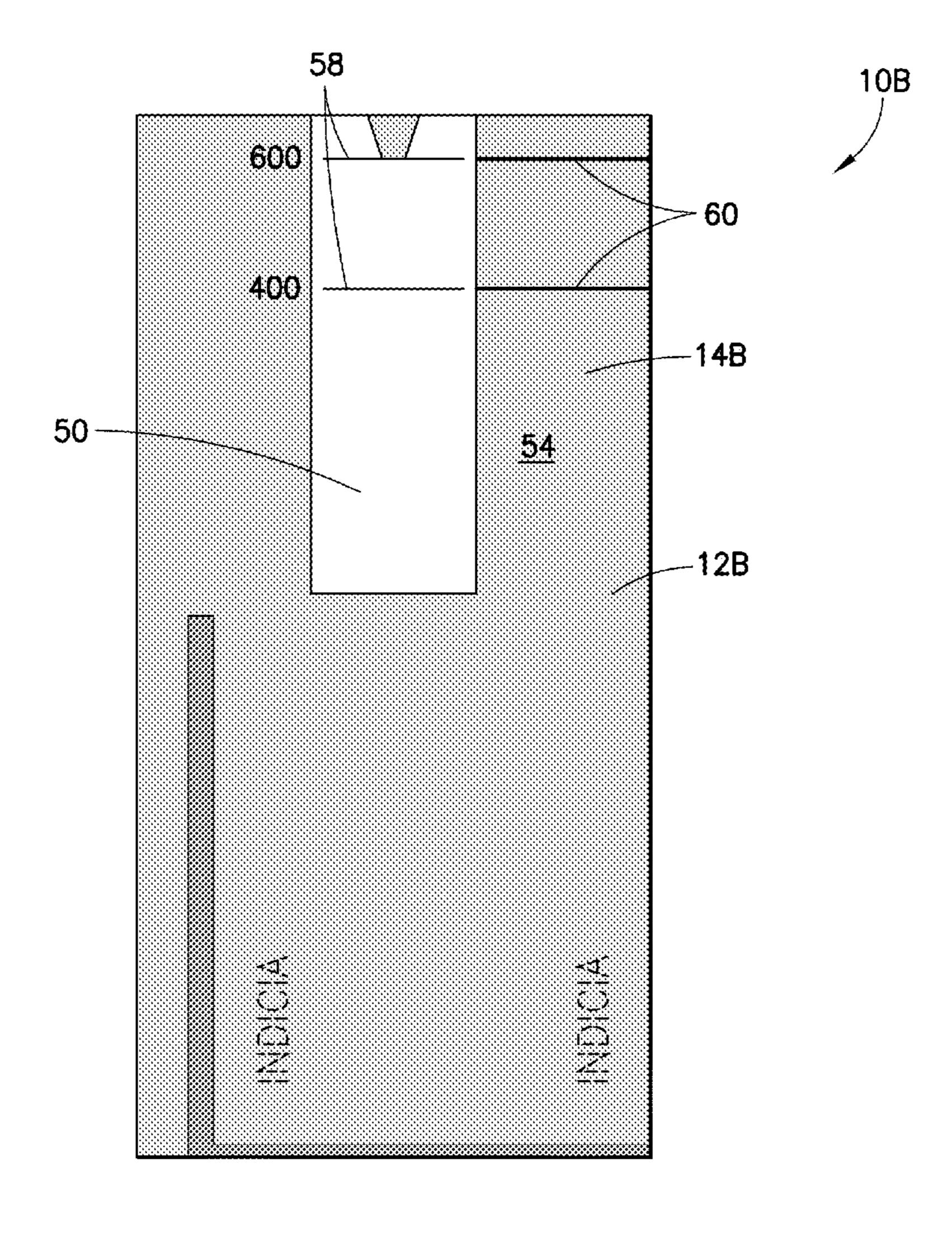


FIG.8

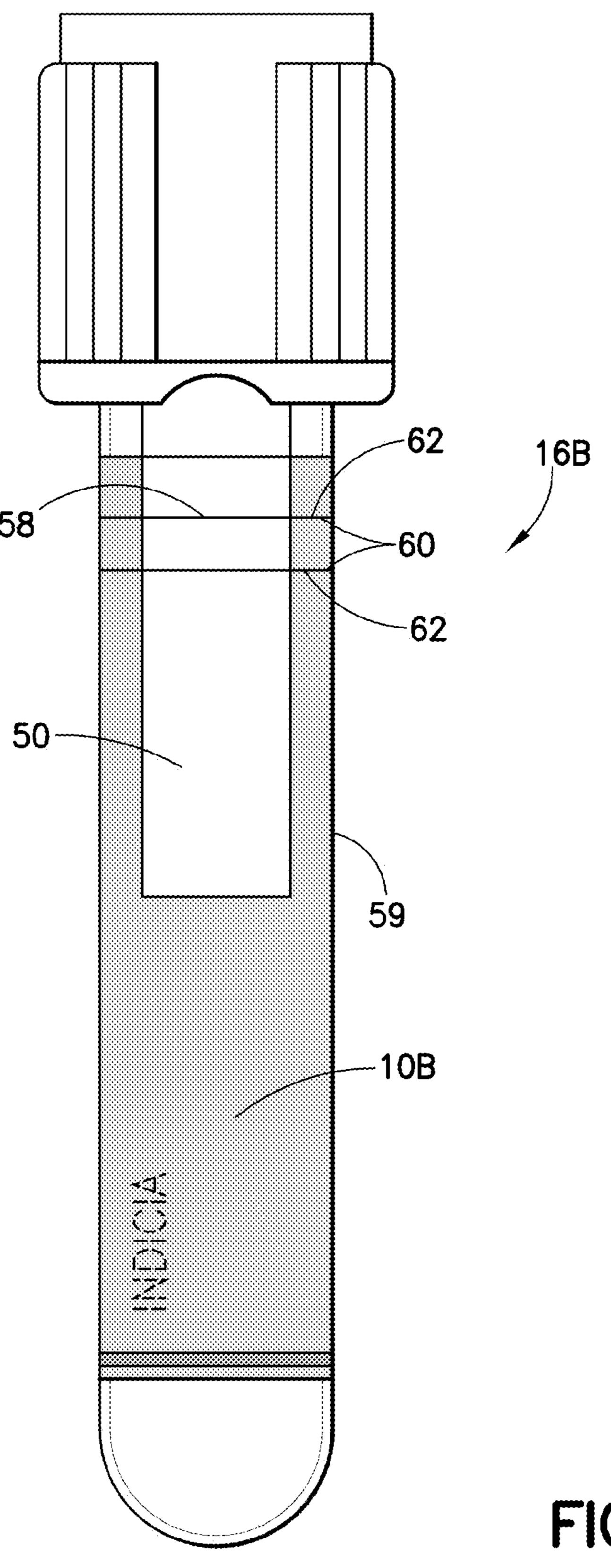


FIG.9

10C

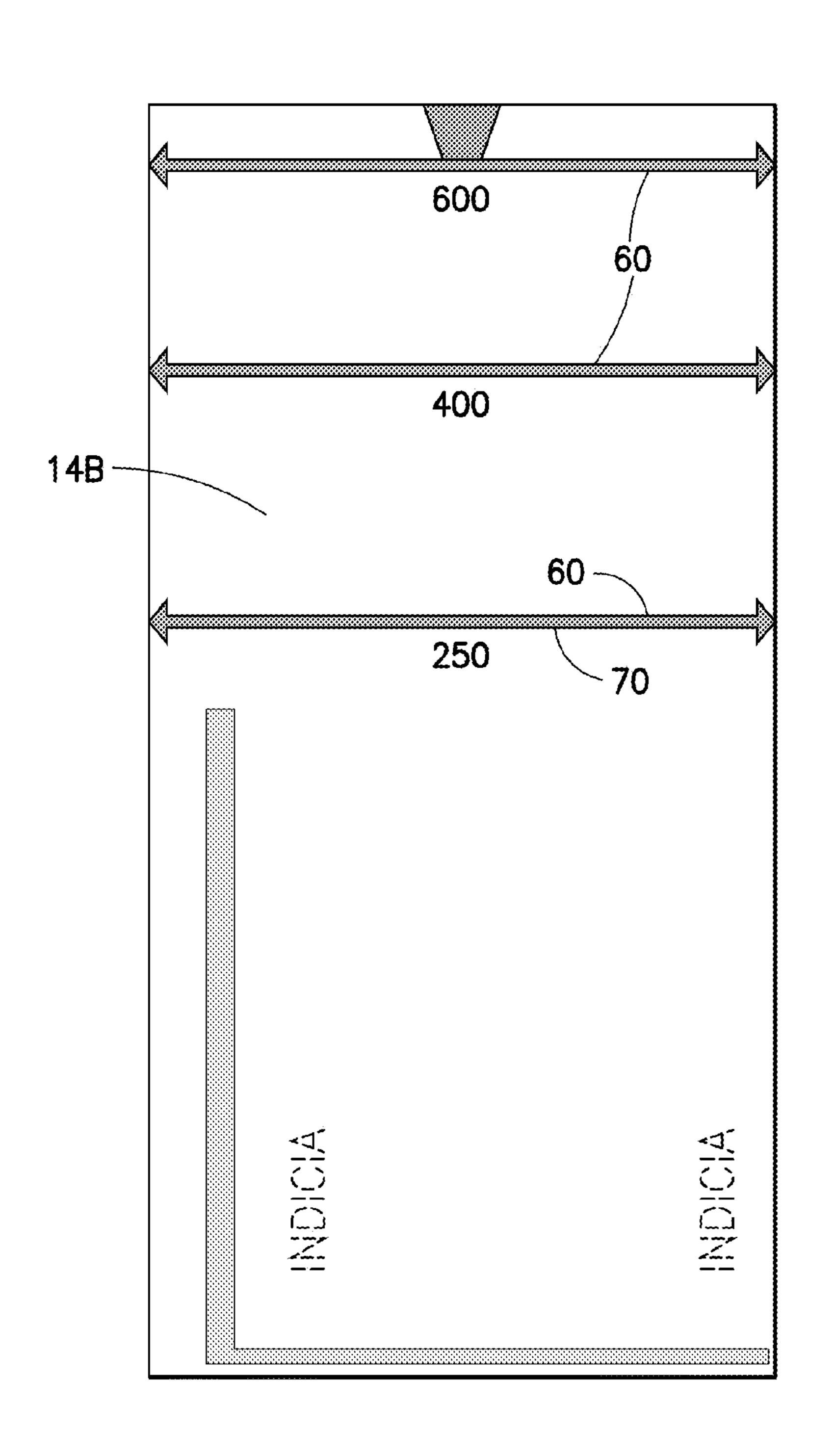


FIG. 10

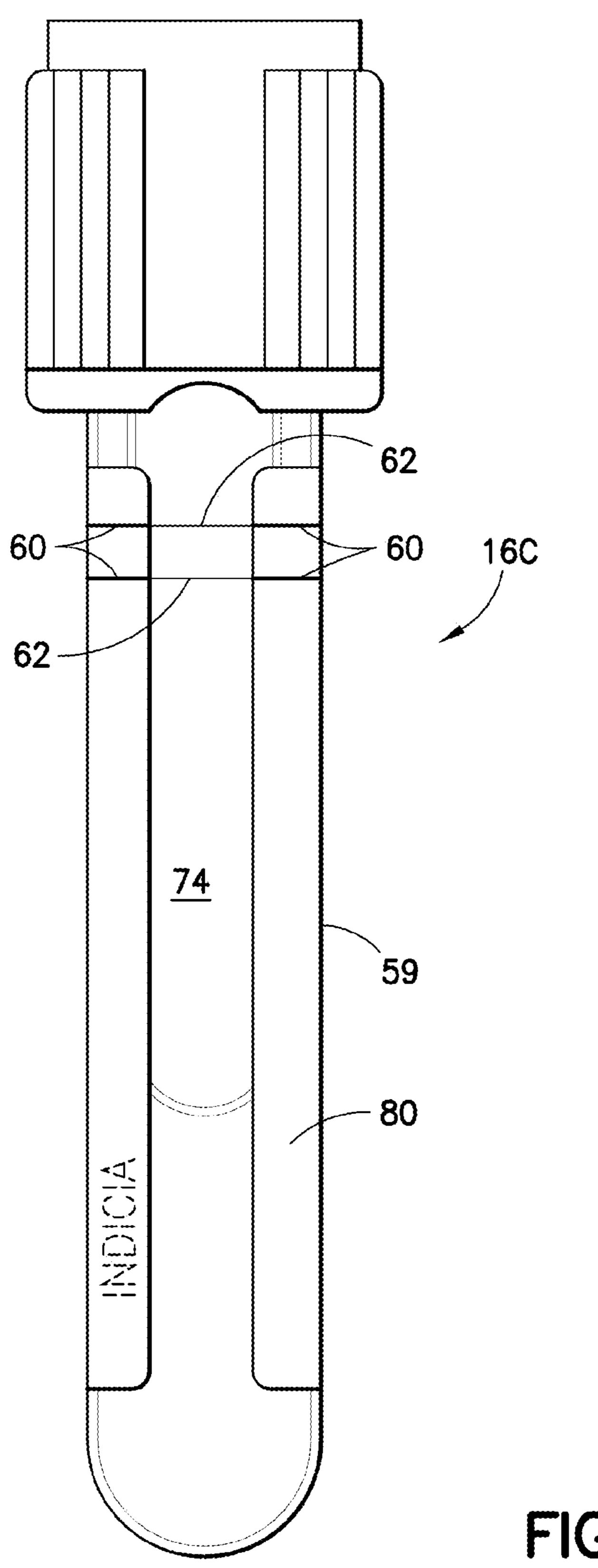
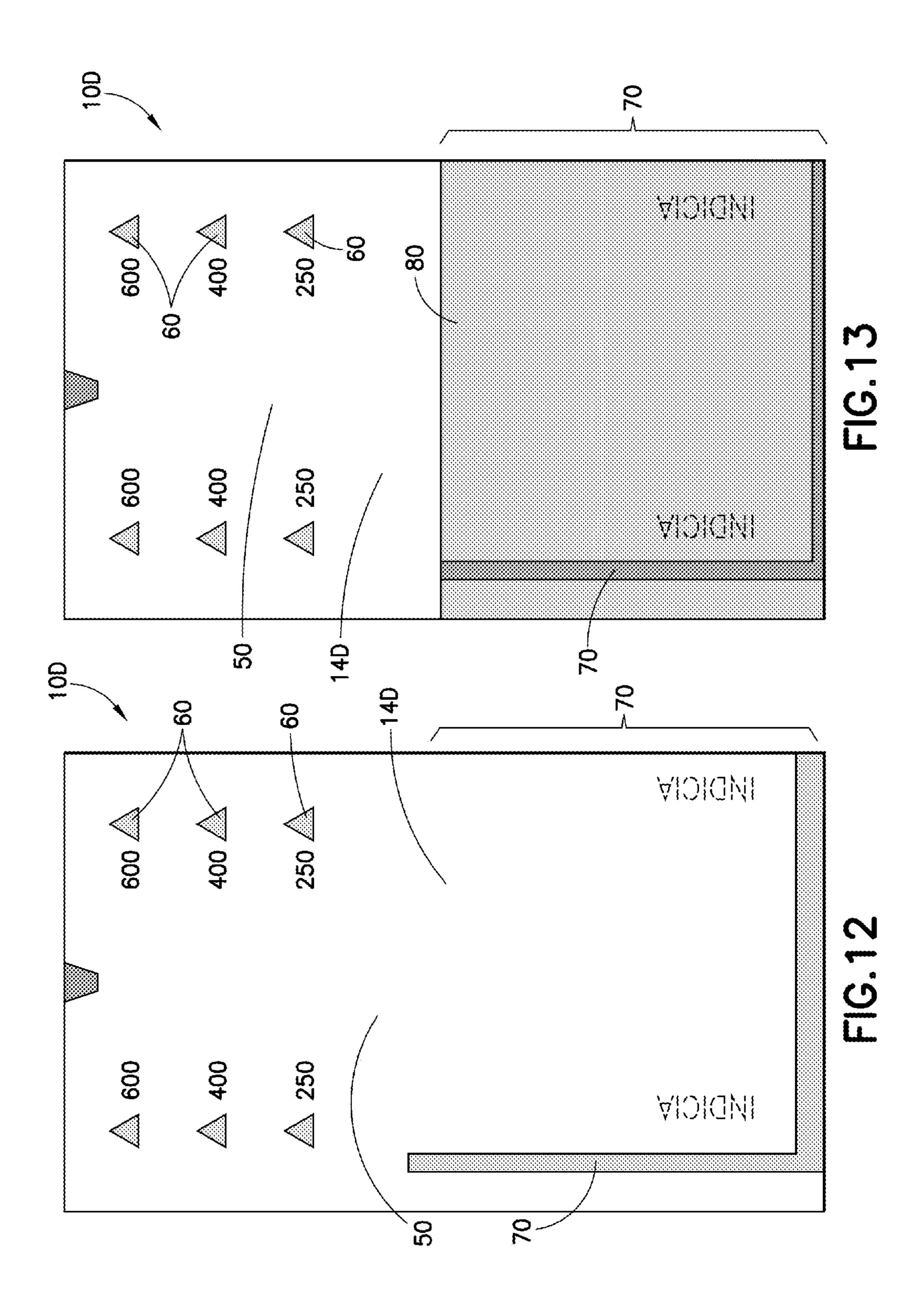
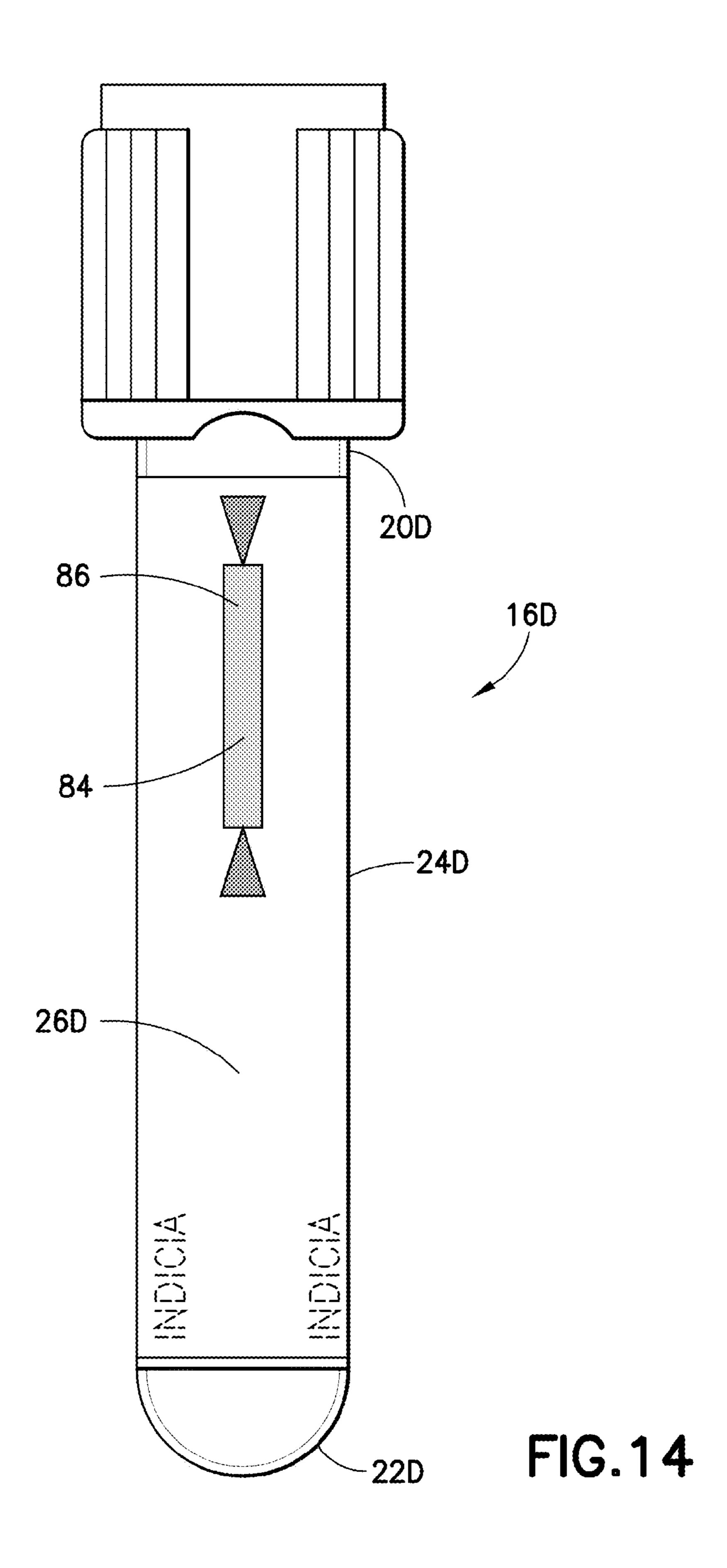


FIG. 11





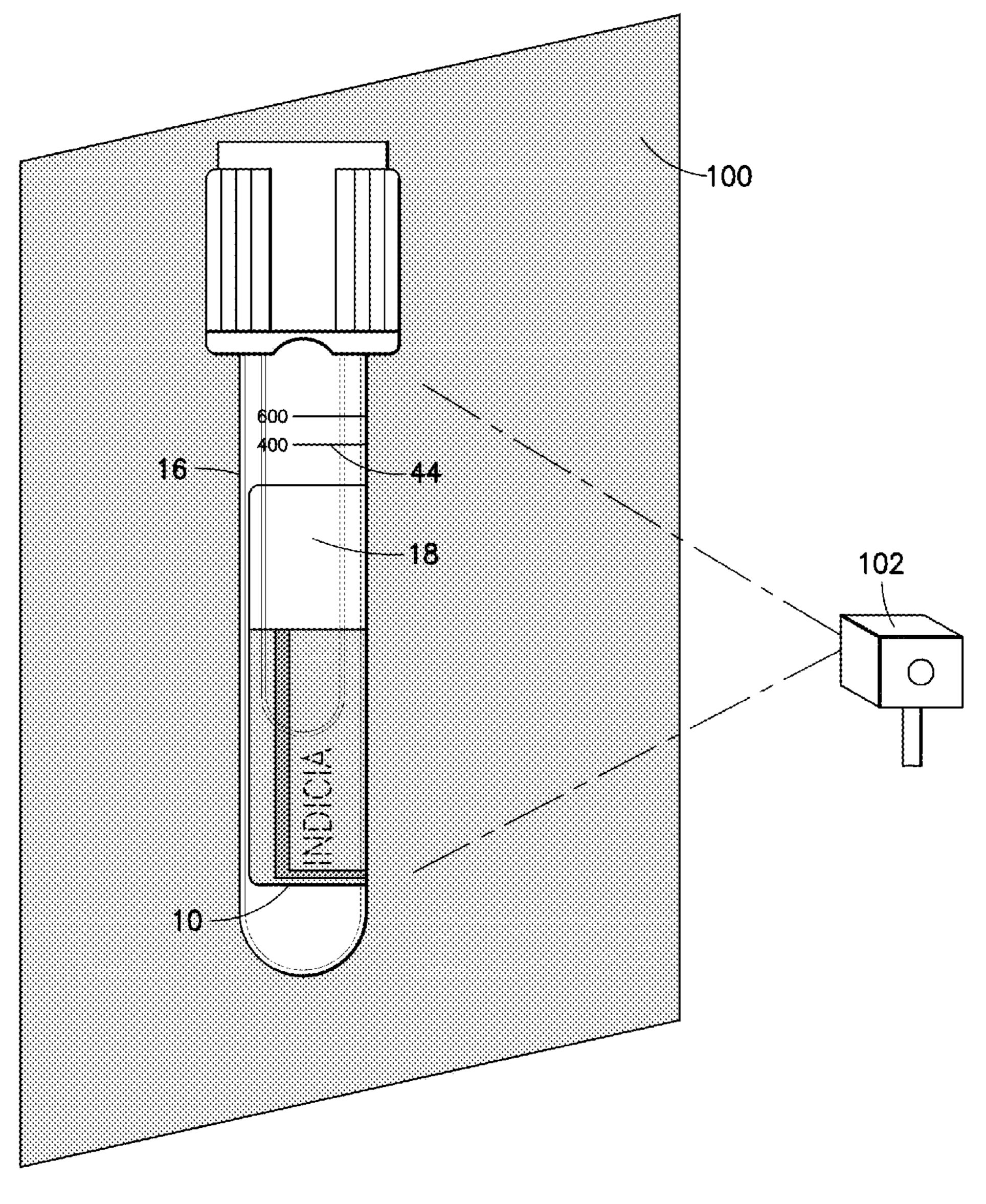


FIG. 15

SPECIMEN CONTAINER LABEL FOR AUTOMATED CLINICAL LABORATORY PROCESSING SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATION

This application is a divisional application of U.S. patent application Ser. No. 13/295,251, filed on Nov. 14, 2011, entitled "Specimen Container Label for Automated Clinical 10 Laboratory Processing Systems", which claims priority to U.S. Provisional Patent Application No. 61/415,665, filed Nov. 19, 2010, entitled "Specimen Container Labeling for, Automated Clinical Laboratory Processing Systems", the entire disclosures of each of which are herein incorporated 15 by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to labels and labeling systems for use in connection with specimen collection containers. More specifically, the present invention relates to labels and labeling systems for specimen collection containers that do not interfere with conventional automated pro- 25 cessing systems.

Description of Related Art

As part of automated clinical laboratory specimen processing, color-based image analysis is typically used to evaluate whether a sufficient volume of specimen is present 30 within a specimen collection container to perform a specified diagnostic or evaluation testing procedure. Many testing procedures require a specified minimum volume of a biological sample in order for an accurate result to be deterdetermined from a typical blood sample, a minimum specimen level is required in order to perform most tests.

In order to determine whether a sample has a sufficient volume or specimen level, a color image of the specimen collection container housing the specimen is taken against a 40 white or other colored background. If the image indicates that the volume of sample is sufficient to perform the test, then the specimen collection container is analyzed accordingly. If the image indicates that an insufficient volume is present within the specimen collection container, then the 45 specimen collection container and contents are discarded.

Most specimen collection containers include at least one label disposed on the surface of the container. Labels typically include information pertaining to patient identification, collection dates, and/or the intended testing procedure to be 50 performed on the sample. Labels typically interfere with the image capturing process for evaluating the volume of specimen housed within the specimen collection container because most systems cannot view the specimen volume through the label. Accordingly, some imaging systems may 55 rotate the specimen collection containers to visualize a label-free window for the analysis. Imaging systems typically include an automated viewer operating with a redgreen-blue (RGB) sensor to detect color variations and color levels correlating to specimen volumes. Any printing on the 60 specimen collection container, including fill lines, lot numbers, or manufacturing logos can generate an error during specimen volume detection due to the color-based analysis of the contents of the specimen collection container. This is particularly true for any printing that may be covered by the 65 backside of a label placed on the exterior surface of the specimen collection container.

Accordingly, a need remains for a label and labeling system for reducing the interference of labels, fill lines, lot numbers, manufacturing logos, and the like, which interfere with color-based imaging processes.

SUMMARY OF THE INVENTION

In accordance with an embodiment of the present invention, a label for application to a specimen collection container for automated viewing against a colored background is disclosed. The label includes a label body having a top surface and a bottom surface adapted for affixation to a specimen collection container, with the label body having a visualization window extending therethrough. The top surface includes printing thereon having a color substantially identical to a color of the background against which the label will be viewed.

The label may include a plurality of visualization windows extending between the top surface and the bottom 20 surface. The label may also include additional printing disposed over the printing, with the additional printing having a second color, the second color being different from the color substantially identical to the color of the background. A flood coating may also be provided with the label, wherein the printing is disposed over the flood coating. In certain configurations, at least a portion of the label body is clear. In other configurations, at least a portion of the label body is white.

The label body may include at least one fill line. Optionally, the top surface of the label includes at least one fill line. In a further configuration, the visualization window includes at least one fill line, the fill line having a color substantially identical to the color of the background against which the label will be viewed. In still other configurations, a specimen mined. For example, in order for an accurate result to be 35 collection container may be provided in contact with the bottom surface of the label body.

> In accordance with another embodiment of the present invention, a label for application to a specimen collection container for automated viewing against a colored background is disclosed. The label includes a label body having a top surface having printing thereon, and a bottom surface adapted for affixation to a specimen collection container, the label body having a visualization window extending therethrough. The bottom surface has a color substantially identical to a color of the background against which the label will be viewed.

> The label body may include at least one fill line. The top surface of the label may optionally include at least one fill line. In a further configuration, the visualization window may include at least one fill line, the fill line having a color substantially identical to the color of the background against which the label will be viewed. In still further configurations, a specimen collection container may be provided in contact with the bottom surface of the label body.

> In accordance with yet another embodiment of the present invention, a specimen collection container for automated viewing against a colored background is disclosed. The specimen collection container includes an open top end, a closed bottom end, and a sidewall extending therebetween forming an interior adapted for receiving a specimen therein. The sidewall includes printing having a color substantially identical to a color of the background against which the specimen collection container will be viewed.

> Optionally, the printing may include at least one fill line. The specimen collection container may also include a label disposed on a portion of the sidewall, with at least a portion of the label aligned with the sidewall including printing. The

printing may include at least one fill line and the label may include at least one fill line aligned with the printing.

In accordance with yet another embodiment of the present invention, a specimen collection container for automated viewing against a colored background is disclosed. The 5 specimen collection container includes an open top end, a closed bottom end, and a sidewall extending therebetween forming an interior adapted for receiving a specimen therein. The sidewall includes colorless indicia having a surface enhancement feature for providing visual distinction from at 10 least a portion of the sidewall.

In certain configurations, the colorless indicia may include at least one fill line. The specimen collection container may also include a label disposed on a portion of the sidewall, with at least a portion of the label aligned with the 15 sidewall including colorless indicia. The colorless indicia may include at least one fill line, and the label may include at least one fill line aligned with the colorless indicia.

In accordance with still a further embodiment of the present invention, a method for viewing a specimen within 20 a specimen collection container is disclosed. The method includes providing a specimen collection container against a colored background. The specimen collection container includes an open top end, a closed bottom end, a sidewall extending therebetween forming an interior adapted for 25 receiving a specimen therein, and a label having a label body disposed over at least a portion of the sidewall, in visual alignment with the colored background. At least one of the sidewall of the specimen collection container and the label body has printing disposed thereon having a color that is 30 substantially identical to the colored background. The method also includes viewing the amount of specimen disposed within the interior of the specimen collection container.

Optionally, the sidewall of the specimen collection container includes printing that is substantially identical to the color of the colored background. The sidewall of the specimen collection container may include printing that is clear. In certain configurations, the printing includes at least one fill line. In other configurations, the label body is clear. The 40 label body may include a top surface and a bottom surface adapted for affixation to a specimen collection container, with the label body having a visualization window extending therethrough. The top surface of the label body may include printing thereon having a color substantially identical to a 45 color of the background against which the label will be viewed. The bottom surface may have a color substantially identical to a color of the background against which the label will be viewed. In further configurations, the method also includes determining whether there is sufficient specimen 50 within the specimen collection container to perform an intended testing procedure. Optionally, viewing the amount of specimen disposed within the interior of the specimen collection container is performed by an automated viewing device.

In accordance with yet a further embodiment of the present invention, a method for viewing a specimen within a specimen collection container includes providing a specimen collection container against a colored background. The specimen collection container includes an open top end, a 60 ment of the present invention. closed bottom end, a sidewall extending therebetween forming an interior adapted for receiving a specimen therein, and a label having a label body disposed over at least a portion of the sidewall, in visual alignment with the colored background. At least one of the sidewall of the specimen col- 65 lection container and the label body includes colorless indicia having a surface enhancement feature for providing

visual distinction from at least another portion of the sidewall or the label body. The method also includes viewing the amount of specimen disposed within the interior of the specimen collection container.

In certain configurations, the method also includes determining whether there is sufficient specimen within the specimen collection container to perform an intended testing procedure. In other configurations, viewing the amount of specimen disposed within the interior of the specimen collection container is performed by an automated viewing device.

Further details and advantages of the invention will become clear upon reading the following detailed description in conjunction with the accompanying drawing figures, wherein like parts are designated with like reference numerals throughout.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front view of a label having a visualization window and fill lines in accordance with an embodiment of the present invention.

FIG. 2 is a front view of a label having an extended visualization window and fill lines in accordance with an embodiment of the present invention.

FIG. 3 is a front view of a specimen collection container having the label of FIG. 2 disposed thereon in accordance with an embodiment of the present invention.

FIG. 4 is a front view of a label having two visualization windows and fill lines in accordance with an embodiment of the present invention.

FIG. 5 is a front view of a label having two visualization windows and fill lines in accordance with an embodiment of the present invention.

FIG. 6 is a front view of a label having two visualization windows and fill lines in accordance with an embodiment of the present invention.

FIG. 7 is a front view of a specimen collection container having the label of FIG. 4 disposed thereon in accordance with an embodiment of the present invention.

FIG. 8 is a front view of a label having a visualization window and fill lines in accordance with an embodiment of the present invention.

FIG. 9 is a front view of a specimen collection container having the label of FIG. 8 disposed thereon in accordance with an embodiment of the present invention.

FIG. 10 is a front view of a label having a flood coating and fill lines in accordance with an embodiment of the present invention.

FIG. 11 is a front view of a specimen collection container having the label of FIG. 10 disposed thereon in accordance with an embodiment of the present invention.

FIG. 12 is a front view of a label having a visualization window and fill indicators in accordance with an embodiment of the present invention.

FIG. 13 is a front view of a label having a visualization window and fill indicators in accordance with an embodi-

FIG. 14 is a front view of a specimen collection container having a physical fill line and a label disposed thereover in accordance with an embodiment of the present invention.

FIG. 15 is a perspective schematic view of a system for viewing a specimen collection container having a label disposed thereon against a colored background in accordance with an embodiment of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

For purposes of the description hereinafter, spatial orientation terms, if used, shall relate to the referenced embodiment, as it is oriented in the accompanying drawing figures or otherwise described in the following detailed description. However, it is to be understood that the embodiments described hereinafter may assume many alternative variations and embodiments. It is also to be understood that the specific devices illustrated in the accompanying drawing figures and described herein are simply exemplary and should not be considered as limiting.

The present invention is directed to a label, specimen collection container, and system for labeling in which any required printed information, such as any patient information, required tests, and/or fill lines, is not distinguishable from either the imaging background color or the underside color of the label. By structuring the printed information 20 such that it is not distinguishable from either the imaging background color and/or the underside color of the label, automated imaging sensing systems do not detect the information, and thus the volumetric analysis may proceed without disruption or error.

With reference to FIG. 1, a label 10 may include a label body 12 having a top surface 14 and an opposing bottom surface (not shown) adapted for affixation to a specimen collection container 16, as shown in FIG. 3. In one embodiment, the bottom surface of the label 10 may include an 30 adhesive for securement to the specimen collection container 16. The specimen collection container 16 may include an open top end 20, a closed bottom end 22, and a sidewall 24 extending therebetween, defining a container interior 26 adapted to receive a specimen, such as a biological speci- 35 men, such as blood, therein. In certain configurations, the specimen collection container 16 may be a single walled container formed of glass and/or a polymeric composition. In other configurations, as shown in FIG. 3, the specimen collection container 16 may include a tube-in-tube configuration in which a second specimen collection container 28 is disposed within the container interior 26. The second specimen collection container 28 may include a closed bottom end 30, an open top end 32, and a sidewall 34 extending therebetween defining a second container interior **36**. The 45 open top end 32 of the second specimen collection container 28 may be joined or otherwise secured with the open top end 20 of the specimen collection container 16, such that introduction of a specimen into the specimen collection container 16 also introduces the specimen into the second container 50 interior 36. A closure 38 may cover the open top end 20 of the specimen collection container 16 and the open top end 32 of the second specimen collection container 28.

Referring again to FIG. 1, the label body 12 may include a visualization window 18 extending through the label body 55 sca 12, such as extending from the top surface 14 to the bottom surface (not shown). When the label 10 is applied to a specimen collection container 16, as shown in FIG. 3, a specimen deposited within the container interior 26 and/or second container interior 36 may be visible through the visualization window 18. In certain embodiments, the visualization window 18 may be a cut-out portion of the label 10. In other embodiments, the visualization window 18 may be a clear portion of the label 10, such as a clear film portion. The label body 12 may also include an opaque region 40 on 65 enlawhich indicia, such as patient identification, intended test identifiers, lot and batch information, tube specifications, the

6

and manufacturer information may be printed. Indicia printed on a top surface 42 of the opaque region 40 may include various colors.

The label body 12 may also include additional indicia 44 that is printed on a portion of the label 10 separate from the opaque region 40. This additional indicia 44 may include fill lines or other information pertaining to the specimen collection container and/or the contents therein. The additional indicia 44 may be printed on the label body 12, such as on 10 the top surface 14 of the label body 12, in a color that is substantially identical to the color of the background against which the specimen collection container 16 will be analyzed by an automated viewer. Accordingly, if the specimen collection container 16 is analyzed against a white background 15 to determine if sufficient volume of specimen is present within the specimen collection container 16 to perform a specified testing procedure, then white additional indicia 44 would be printed on the label body 12. Similarly, if the specimen collection container 16 is analyzed against a yellow background, then yellow additional indicia 44 would be printed on the label body 12. By substantially matching the color of the additional indicia 44 to the color of the background against which the specimen collection container 16 will be analyzed, the indicia is visible to a clinician 25 during specimen collection but is not detected by the automated viewer during volumetric analysis. Accordingly, a clinician may be able to view a fill line printed in white on a label 10 disposed on a specimen collection container 16 during a blood draw, but the white fill line is not detected by the automated viewer and thus does not generate an error during the serum level analysis.

In certain embodiments, the opaque portion 40 may extend around only a portion of the sidewall 24 of the specimen collection container 16. Accordingly, in certain embodiments, the bottom surface (not shown) of the label body 12, specifically the bottom surface of the opaque portion 40, may have a color that is substantially identical to the color of the background against which the specimen collection container 16 is analyzed. Accordingly, if the specimen collection container 16 is analyzed against a white background, then the bottom surface of the opaque portion 40 of the label body 12 may also be white. In this configuration, the automated viewer would not be disrupted if the specimen collection container 16 was rotated such that the bottom surface of the label body 12 was positioned such that it would be provided in visual contact with the viewer through the opposing side of the specimen collection container 16, i.e., as seen through the back of the specimen collection container 16.

For purposes of illustration it is noted that throughout the present application, portions of the label 10 indicated as being clear are shown in the accompanying figures as being white in color, and that portions of the label 10 indicated as being white are shown in the accompanying figures in grey scale. Accordingly, with reference to FIG. 1 for example, the opaque portion 40 is shown as having a white background, whereas the visualization window 18 is shown as being clear. Similarly, the additional indicia 44 is shown as being white in color as printed on the clear visualization window 18.

Referring to FIG. 2, in certain situations a label 10A having an enlarged visualization window 18A may be desirable. This may be particularly true during a small volume blood draw in which the clinician desires to visualize an enlarged viewing area of the contents of the specimen collection container 16. Accordingly, in this configuration, the relative proportioning of an opaque portion 40A and the

visualization window 18A may be adjusted to provide a reduced area opaque portion 40A and an increased area visualization window 18A. As shown in FIGS. 1-3, at least a portion of the label body 12 may be clear. In other situations, it may be desired that the entire label body 12 5 may be clear, with additional printing indicia 44 having a color substantially identical to the color of the background against which the tube will be viewed. In another configuration, at least a portion of the label body 12 may be white. In other situations, it may be desired that the entire label 10 body 12 be white, with additional printing indicia 44 having a color substantially identical to the color of the background against which the tube will be viewed.

Referring to FIGS. 4-6, in certain configurations a label body 12B of a label 10B may include a plurality of visual- 15 ization windows 18B, such as a first visualization window 50 and a second visualization window 52 extending between a top surface 14B and the bottom surface (not shown) opposing the top surface 14B. As shown in FIG. 4, the first visualization window 50 and the second visualization win- 20 dow 52 may be disposed within an opaque portion 40B. In another configuration, the first visualization window 50 and the second visualization window 52 may be oriented in a substantially vertical orientation such that when the label body 12B is positioned on a specimen collection container 25 16B, as shown in FIG. 9, a clinician may view the amount of specimen being deposited within the specimen collection container 16B during specimen draw, and an automated viewer may determine the volume of specimen present within the specimen collection container 16B for subsequent 30 analysis.

Referring again to FIG. 4, in one embodiment, the label body 12B may include a first visualization window 50 and a second visualization window 52 disposed within the interior region **54**. The label body **12**B may also include other indicia 60, such as fill lines, printed on the top surface **14**B. As shown in FIG. **4**, the fill lines or other indicia **60** may be provided adjacent the first visualization window 50 and/or the second visualization window 52 to enable a 40 clinician to easily view the amount of sample being introduced into the specimen collection container 16B during specimen draw.

In certain situations, the automated viewer may require a label-free area for performing specimen volume analysis, 45 and will rotate the specimen collection container in search of a viewable area. Accordingly, it may be necessary to dimension and position the visualization window 50 such that the automated viewer does not mistake the visualization window **50** for a label-free area, which may be defined as the 50 gap between leading and trailing edges of the label. For example, for testing performed on standard specimen collection containers having an outer diameter of from 10-16 mm and an overall height of from 75-100 mm, the minimum required label-free area for volume analysis may be 6.5 mm 55 and must extend the entire length or height of the specimen collection container. Accordingly, in one embodiment, the visualization window 50 may have a length that is less than 6.5 mm and have a height that is less than the height of the overall label.

Referring to FIG. 5, in accordance with another embodiment, the label body 12B may include a first visualization window 50 and a second visualization window 52 disposed adjacent a perimeter 56 of the label body 12B. In certain configurations, the label body 12B may include other indicia 65 60, such as fill lines, printed on the top surface 14B. As previously described herein, the label body 12B may be

affixed to a specimen collection container 16B. Optionally, at least one of the first visualization window 50 and the second visualization window 52 include additional indicia 58 having the same color as the background color against which the specimen collection container 16B will be viewed. In certain configurations, the additional indicia 58 disposed on or within the first and/or second visualization windows 50, 52 may be at least partially aligned with the other indicia 60 present on the label body 12B. In this embodiment, the other indicia 60 present on the label body 12B may be of any color, whereas the additional indicia 58 present on the first visualization window 50 and/or the second visualization window 52 has the same color as the background color against which the specimen collection container **16**B will be viewed.

The labels 10, 10A, 10B of the present invention may be disposed on a wide variety of specimen collection containers 16, 16B. Accordingly, the size of the label may be adjusted accordingly to accommodate either larger or smaller specimen collection container exterior surface areas. As shown in FIG. 6, a widened label 10B may be provided such that when applied to the surface of the specimen collection container 16B, as shown in FIG. 9, the label 10B may cover a portion of an exterior surface 59 of the specimen collection container 16B extending up to about 270° of the circular perimeter of the specimen collection container 16B. In one embodiment, the label 10B may cover any suitable portion of the exterior surface 59 of the specimen collection container 16B, such as from about 180° extending up to about 360° of the circular perimeter of the specimen collection container 16B.

Referring to FIGS. 8-9, in certain configurations, a single visualization window 50 may be disposed within the interior region of the label body 12B, such as within the interior interior region of the label body 12B, such as within an 35 region 54. As described hereinabove, the top surface 14B of the label body 12B may include a printed other indicia 60 and/or additional indicia 58 disposed within or on the visualization window 50. When the label 10B is applied to the exterior surface 59 of the specimen collection container 16B, at least a portion of the other indicia 60, such as fill lines, printed on the top surface 14B of the label body 12B and/or the additional indicia 58 disposed on or within the visualization window 50, may be aligned with a printing 62, such as a fill line, disposed on the specimen collection container 16B. In certain situations, at least a portion of the other indicia 60 and/or the additional indicia 58 may cover a portion of the fill line 62 of the specimen collection container 16B.

Referring to FIGS. 10-11, in one embodiment, the label 10C includes other indicia 60 or printing having a color substantially identical to a color of the background against which the label will be viewed, as previously discussed herein. In certain situations, however, it may be desirable to provide indicia 60 or other printing that has a color different from the background color, yet does not create the errors in visual analysis as previously discussed. In these situations, the indicia 60 may include additional printing 70 disposed over the indicia 60 that has a color that is different from the color of the background. For example, if a specimen collection container 16C having a label 10C disposed thereon is to be viewed against a white background, then the other indicia 60 may be initially printed on the label 10C and/or specimen collection container 16C in white. Subsequently, a printing 70 having a second color, such as black, may be printed over the indicia 60. Accordingly, when the label 10C of the specimen collection container 16C is viewed from the front, such as looking directly at the label 10C disposed on

9

the exterior surface of the specimen collection container 16C, then the black printing is visible. When the label 10C of the specimen collection container 16C is viewed from the back or bottom surface, such as when the interior surface of the tube is viewed through either a visualization window, as discussed above, or a portion of a tube 74 that is not covered by the label 10C, then the white printing is visible. Accordingly, in this configuration, the clinician may have the benefit of viewing easily discernable black print, whereas the automated viewer visualizes the white print and does not process the black print disposed thereover.

In another configuration, a flood coating 80 of a first color that is substantially identical to the background color against which the specimen collection container 16C will be viewed may be provided over at least a portion of the label 10C and/or the specimen collection container 16C. The flood coating 80 may be printed over a larger region of the label 10C and/or specimen collection container 16C than the indicia 60. In this configuration, a printing 70, having a 20 second color that is different from the background color may be printed over the flood coating 80 in a similar manner as described above. A benefit of utilizing a flood coating 80 is that the alignment of the printing 70 does not need to be as precise as when the printing 70 is disposed over other indicia 25 **60**. For example, if a white fill line having a 1 mm thickness is printed on a clear label as indicia 60, and a 1 mm black fill line printing 70 is printed over the white fill line indicia 60, then the alignment between the indicia 60 and the printing 70 must be perfect in order to prevent inadvertent 30 portions of the printing 70 to be visible from the bottom surface of the label 10C and viewable by an automated viewer. Accordingly, the thickness of the printing 70 may be reduced, or a larger flood coating 80 may be deposited over the label 10C and/or specimen collection container 16C to 35 increase the printing tolerance.

Referring again to FIGS. 10-11, when the label 10C is applied to the exterior surface 59 of the specimen collection container 16C, at least a portion of the other indicia 60 printed on the top surface 14B of the label 10C, and/or the 40 additional indicia 58 disposed on or within the visualization window 50, as shown in FIGS. 8-9, may be aligned with a printing 62. Printing 62 may include a fill line, disposed on the specimen collection container 16C. In certain situations, at least a portion of the other indicia 60 and/or the additional 45 indicia 58 may cover a portion of the printing 62 of the specimen collection container 16C. The printing 62 on the specimen collection container 16C may have a color that is substantially identical to the color of the background against which the specimen collection container will be viewed. As 50 shown in FIG. 11, the printing 62 may include one or more fill lines.

Referring to FIGS. 12-13, alternative labels 10D are shown in which the other indicia 60 may include fill indicators and volumetric representations. FIG. 12 illustrates the 55 other indicia 60 printed within the visualization window 50 in a color that is substantially identical to the background color against a specimen collection container to which the label 10D would be applied would be viewed. Additional printing 70 in various colors that are different from the 60 background color are shown printed over corresponding indicia 60 such that the additional printing 70 in the various colors is visible only from a top surface 14D of the label 10D. Similarly, FIG. 13 illustrates the identical label with the additional printing 70 in various colors that are different 65 from the background color shown printed over a flood coating 80 having the same color as the background color.

10

Referring to FIG. 14, a specimen collection container 16D for automated viewing against a colored background includes an open top end 20D, a closed bottom end 22D, and a sidewall 24D extending therebetween forming an interior 26D adapted for receiving a specimen therein. The specimen collection container 16D may include printing on the sidewall 24D, such as disposed on an exterior surface of the sidewall 24D or disposed within a portion of the sidewall 24D. As described above, the printing may be of a color that is substantially identical to the color of a background against which the specimen collection container 16D is viewed. The printing may include a fill line indicator and/or identifying indicia, as described above.

Referring again to FIG. 14, the sidewall 24D of the 15 specimen collection container 16D may include colorless indicia 84 having a surface enhancement feature 86 for providing visual distinction from at least a portion of the sidewall 24D. The surface enhancement feature 86 may be provided by etching, knurling, or in-molding the colorless indicia **84** into the specimen collection container **16**D. In a further embodiment, the surface enhancement feature 86 provides a difference in surface texture to create a visual distinction between the colorless indicia **84** and the sidewall **24**D of the specimen collection container **16**D. In a further embodiment, the colorless indicia may include at least one fill line. The colorless indicia 84 may be provided in any orientation, such as substantially vertical or substantially horizontal. The colorless indicia may extend up to a full or partial length or circumference of the specimen collection container 16D.

Referring to FIG. 15, a specimen collection container 16 having a label 10 disposed thereon and having a biological specimen disposed therein is provided against a colored background 100. The specimen collection container 16 is aligned with a camera or other electronic eye 102 which allows the specimen collection container 16 to be analyzed by the electronic eye 102. The electronic eye 102 determines whether there is sufficient volume of specimen disposed within the specimen collection container 16 to perform an intended testing procedure. The electronic eye **102** may view the sufficiency of the specimen within the specimen collection container 16 by reference to indicia 44, such as a fill line. The electronic eye 102 may also view the sufficiency of the specimen within the specimen collection container 16 through the visualization window 18. As described herein, the indicia 44 and the background 100 have substantially the same color so as not to permit the indicia 44 to interfere with the electronic eye 102. In a further embodiment, the indicia **44** is colorless and has a surface enhancement feature **86** for providing visual distinction from at least another portion of the specimen collection container 16. In this system, analyzing the volume of the contents of the specimen collection container 16 by the electronic eye 102 includes determining whether there is sufficient specimen within the specimen collection container to perform an intended testing procedure.

In certain configurations, the provision of the specimen collection container 16 having a biological sample disposed therein against the colored background 100, and the analyzing of the volume of the contents of the specimen collection container 16 may be partially or fully automated. If the image indicates that the volume of sample is sufficient to perform the test, then the specimen collection container is analyzed accordingly. If the image indicates that an insufficient volume is present within the specimen collection container, then the specimen collection container and contents are discarded.

30

11

While several embodiments of a label, a specimen collection container, and an automated process for analyzing the volume of a specimen collection container have been described in the foregoing detailed description, those skilled in the art may make modifications and alterations to these 5 embodiments without departing from the scope and spirit of the invention. Accordingly, the foregoing description is intended to be illustrative rather than restrictive.

What is claimed is:

1. A specimen collection container for automated viewing 10 against a colored background, comprising:

an open top end;

- a closed bottom end; and
- a sidewall extending therebetween forming an interior adapted for receiving a specimen therein, wherein a ¹⁵ material that forms the sidewall includes colorless indicia integrated with the material and having a surface enhancement feature for providing visual distinction from at least a portion of the sidewall, wherein the colorless indicia comprises at least one fill line; ²⁰
- a label disposed on a portion of the sidewall, wherein the label comprises at least one fill line aligned with the at least one fill line of the colorless indicia.
- 2. A method for viewing a specimen within a specimen collection container, comprising:

providing the specimen collection container against a colored background, the specimen collection container comprising:

an open top end;

a closed bottom end;

- a sidewall extending therebetween forming an interior adapted for receiving the specimen therein; and
- a label having a label body disposed over at least a portion of the sidewall, in visual alignment with the colored background, wherein a material that forms the sidewall of the specimen collection container comprises colorless indicia integrated with the material and having a surface enhancement feature for providing visual distinction from at least another portion of the sidewall; and

automated viewing the amount of specimen disposed within the interior of the specimen collection container,

12

wherein at least a portion of the label is aligned with the sidewall including colorless indicia, wherein the colorless indicia comprises at least one fill line and the label comprises at least one fill line aligned with the colorless indicia, wherein the at least one fill line of the label has a color that is substantially identical to the entire colored background, wherein the colored background is external to the specimen collection container, and wherein the automated viewing is performed from a side facing the at least one fill line of the label.

- 3. The method of claim 2, further comprising determining whether there is sufficient specimen within the specimen collection container to perform an intended testing procedure.
- 4. The method of claim 2, wherein viewing the amount of specimen disposed within the interior of the specimen collection container is performed by an automated viewing device.
- 5. A system for automated viewing of a specimen collection container against a colored background, comprising:

the colored background;

- a specimen collection container comprising: an open top end;
 - a closed bottom end; and
 - a sidewall extending therebetween forming an interior adapted for receiving a specimen therein, wherein a material that forms the sidewall includes colorless indicia integrated with the material and having a surface enhancement feature for providing visual distinction from at least a portion of the sidewall; and
- a label disposed on a portion of the sidewall, at least a portion of the label aligned with the sidewall including colorless indicia, wherein the colorless indicia comprises at least one fill line and the label comprises at least one fill line aligned with the colorless indicia, wherein the at least one fill line of the label has a color that is substantially identical to the entire colored background, wherein the colored background is external to the specimen collection container, and wherein the automated viewing is performed from a side facing the at least one fill line of the label.

* * * *